

### **REMARKS**

The non-final Office Action and references cited therein have been carefully studied. Favorable reconsideration and allowance are respectfully requested.

Applicant notes with appreciation the Examiner's acknowledgement that the April 17, 2007, Information Disclosure Statement (IDS) has been received and considered by the U.S.P.T.O.

#### **I. Claim Status and Amendments**

Claims 1-9 were pending in the present application. Claims 1-9 have been examined on the merits and stand rejected.

By way of the present amendment, claim 2 has been cancelled without prejudice and/or disclaimer. Claim 1 has been amended and has incorporated with the subject matter of claim 2. Support for the amendment can be found at least in the original claim 2, the specification, and the drawings. For example, the features "the reservoir (6) ... extends in said second body (4), laterally from said inhaling channel (3), along a longitudinal axis substantially perpendicular to the longitudinal axis (x) of the first body (2)" is supported at least by the passage on page 4, lines 19-22, of the specification. The Figures 1-4 also clearly show that the reservoir is defined by the second body of the inhaler, and extends and protrudes laterally from the first body. Claims 3-6 and 8-9 have also been amended in a non-narrowing manner to correspond to the cancellation of claim 1 and to correct errors in grammar. Claim 7 has been amended to address an antecedent basis issue. As such, no new matter is added.

Claims 1 and 3-9 are pending upon entry of this amendment. These claims define patentable subject matter and should be allowed.

## **II. Foreign Priority**

In item 2 of the Office Action, the Examiner has acknowledged applicant's claim for foreign priority based on an application MO2004A000060 filed in Italy on March 18, 2004. However, the Examiner asserts that applicant has not filed a certified copy of the MO2004A000060 application as required by 35 U.S.C. 119(b).

Applicant respectfully notes that the present application, claiming foreign priority based on MO2004A000060, is a national phase entry of the PCT patent application No. PCT/EP05/51181. A certified copy of the priority document will have been filed by the International Bureau of WIPO in the U.S.P.T.O. according to the PCT convention. The Examiner therefore is respectfully to confirm that such document was received by the U.S.P.T.O.

To facilitate the prosecution, however, Applicant encloses herewith two documents to prove the transmission of the priority document to the WIPO. The two documents are the PCT Notification Concerning Submission or Transmittal of Priority Document and the cover sheet attached to the copy of the priority document from WIPO. Acknowledgement of the reception of the certified copy of the MO2004A000060 application is respectfully requested.

## **III. Drawings**

The drawings have been objected to in item 3 of the Office Action as failing to comply with 37 CFR 1.84(p)(5) because they do not include reference number "3c" in the specification. Applicant has amended Figures 1, 2, and 4 to include the reference number --3c-- as suggested by the Examiner. Withdrawal of this objection is respectfully requested.

**IV. Specification**

The abstract has been objected to in item 5 of the Office Action as the terms “the 5 outside” in line 4 and the term “10 making” in line 10 thereof are confusing; the disclosure is also objected to on the basis of informality as stated in item 6 of the Specification. Applicant has amended the abstract and the paragraph beginning on page 2, line 19 of the specification to address the issues raised by the Examiner. Withdrawal of the objections is therefore respectfully requested.

**V. Claim Objection**

Claims 1, 2, 4, 7, and 9 have been objected to on the basis of informalities detailed in item 7 of the Office Action. Applicant has incorporated claim 2 into claim 1 and amended claims 1, 4, 7, and 9, and Figures 1, 2, and 4 to address the informality issue raised by the Examiner. Withdrawal of the objection is therefore respectfully requested.

Applicant understands that no other informality issues and confusion issues exist, and applicant is proceeding in reliance thereof.

**VI. Claim Rejection under 35 U.S.C. §102**

Claims 1-4 and 8-9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application No. 2002/0033177 (“Ohki”) for the reasons in item 9 of the Office Action. This rejection is respectfully traversed.

It is well established that to anticipate a claim, a cited prior art reference must disclose each and every element of the claimed invention. *See*, M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2131. Respectfully, Ohki does not do so.

Independent claim 1, as amended, requires an inhaler including a first and a second body, wherein the first body has an inhaling channel having at least one lateral outlet perpendicular to a longitudinal axis of the first body, the first body is inserted into the second body, and a reservoir formed in the second body extends laterally from the inhaling channel of the first body along an axis perpendicular to the longitudinal axis of the first body and the respective inhaling channel. Ohki does not disclose these features of claim 1.

The § 102 rejection in item 9 relies on Figure 13 of Ohki. Figure 13 of Ohki illustrates a cross sectional view of an inhalant medicator embodiment. While there are some superficial similarities, the inhalant medicator of Ohki's Figure 13 includes a medicator body (41) and a medical powder storage cylindrical member (43), which are distinguished by crosshatchings of different directions. The medicator body (41) has a cylindrical fit hole (42) and an inhalant port (3) extending along the central axis of the medicator body (41). The medical powder storage cylindrical member (43) has a cylindrical portion (44) configured to insert into the cylindrical fit hole (42) so that a medical powder storage chamber (47) is formed therebetween along the central axis. An inflow air passageway (5) extends parallel to and laterally along the central axis of the medicator body (41) and connects the medical powder storage chamber (47) to the inhalant port (3). By rotating the medical powder storage cylindrical member (43) with respect to the medicator body (41) the connection can be opened and closed.

Claim 1 of the present application, as amended, requires that the first body includes the inhalant channel and the second body includes the reservoir. On pages 5-6 of the Office Action, the rejection states that the medical powder storage cylindrical member (43) is a first body and is provided with an inhalant port (3) as an inhaling channel, and the medicator body (41) is a second body and is provided with a medical powder storage chamber (47) as a reservoir. Applicant respectfully disagrees.

The crosshatchings in Figure 13 clearly show that the inhalant port (3) is formed in the medicator body (41). Because the medical powder storage cylindrical member (43) does not include a inhalant channel, the medical powder storage cylindrical member (43) cannot possibly correspond to the first body in claim 1, as the Examiner has interpreted. Similarly, the reservoir (47) is enclosed in the medical powder storage cylindrical member (43), and the medicator body (41) does not include a reservoir, contrary to the Examiner's interpretation. Therefore, the medicator body (41) cannot possibly correspond to the second body in claim 1. Thus, applicant respectfully submits that Ohki does not anticipate claim 1 and the claims which dependent therefrom.

Further, in Figure 13 of Ohki, the inhalant port (3) and the cylindrical fit hole (42) extend along the central axis thereof; and the medical powder storage chamber (47) and the air passageways (5, 6) also extend along the central axis of the medicator body (41). In other words, none of the medicator body (41) and the medical powder storage cylindrical member (43) has an outlet perpendicular to the central axis, and the reservoir (47) is not perpendicular to the central axis as well. Thus, Ohki clearly does not disclose a first body that has an inhaling channel having at least one lateral outlet perpendicular to a longitudinal axis of the first body, and a

reservoir formed in the second body extends perpendicular to the longitudinal axis of the first body and the respective inhaling channel, as called for in claim 1.

Moreover, in Ohki, it is the medical powder storage cylindrical member (43) that is axially inserted into the medicator body (41), *i.e.*, Ohki discloses inserting the element having the reservoir into the element having the inhalant channel. This is apparently contrary to claim 1, which recites that the first body (having the inhalant channel) is inserted into the second body (having the reservoir).

For at least these reasons, Ohki does not anticipate claim 1 of the present application.

In addition, applicant also respectfully submits that the claimed invention is novel over Ohki because the lateral position of the reservoir with respect to the inhaling channel has a simpler structure than the complex internal air passageways (5, 6) in the inhalant medicator of Ohki, and thus the inhaler of the claimed invention has a lower cost and a better manufacturability using the usual injection moulding technique. Also, the claimed invention is also easier to dispense a single dose of preparation in powder form, and therefore is easier to use. As the claimed invention provides an inhaler being structurally simpler, cheaper, and easier to use, it is particularly suitable for a single-use and/or disposable application for inhaling a dose of preparation in powder form.

For at least these reasons, Applicant respectfully submits that claim 1 is patentable over Ohki, and claims 3-4 and 8-9 are also patentable over Ohki at least by virtue of their dependency from claim 1. Withdrawal of the rejection is therefore respectfully requested.

**VII. Claim Rejection under 35 U.S.C. §103**

Claims 5-7 have been rejected under 35 U.S.C. §103(a) as being obvious from Ohki in view of U.S. Patent No. 6,065,472 ("Anderson") for the reasons in item 11 of the Office Action. This rejection is respectfully traversed. The arguments set forth above with respect to Ohki are respectfully repeated by reference.

Applicant respectfully submits that the secondary reference of Anderson does not remedy the above-identified deficiencies of Ohki with respect to claim 1.

Anderson discloses a powder inhalation device (shown in Figure 2 of Anderson). The inhalation device includes a housing, a conduit 8, and a dosing unit 6, 7. However, the conduit 8 clearly does not have a lateral opening and the dosing unit 6, 7 (the reservoir or chamber for receiving and storing the powder medicament to be inhaled) does not extend laterally from the longitudinal axis of the central inhaling channel. Therefore, combining Ohki and Anderson as proposed, even if such a combination were obvious, would at least fail to disclose an inhaling channel having at least one lateral outlet perpendicular to a longitudinal axis of the first body, and a reservoir formed in the second body extends perpendicular to the longitudinal axis of the first body and the respective inhaling channel, as recited in claim 1.

Applicant further respectfully submits that the inhalers disclosed by Ohki and Anderson respectively correspond to very different concepts, each having its proper specific structural and operative features, and in turn appearing as strictly linked to the embodiment of which they are part, and thereby not directly comparable with each other. It is not obvious to modify the inhaler of Ohki with Anderson as proposed by the Examiner so as to render claim 1 of the present application obvious to one of ordinary skill in the art.

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For at least this additional reason, Applicant respectfully submits that claim 1 is patentable over the prior art of record whether taken alone or in combination as proposed in the Office Action, and claims 5-7 are also patentable at least by virtue of their dependency from claim 1 of the present application. Withdrawal of the rejection is therefore respectfully requested.

### **Conclusion**

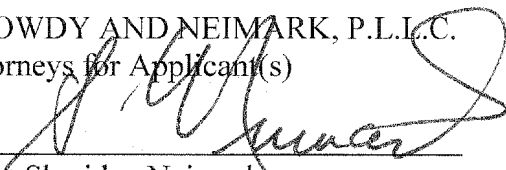
In view of the above amendment and remarks, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections of record. Applicant submits that the application is in condition for allowance and early notice to this effect is most earnestly solicited.

If the Examiner has any questions, he is invited to contact the undersigned at 202-628-5197.

Respectfully submitted,

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